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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/648,123	08/25/2000	Vincent P. Stanton JR.	030586.0009.CIP2	6346

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EXAMINER
WILDER, CYNTHIA B

ART UNIT	PAPER NUMBER
1637	18

DATE MAILED: 03/19/2003

Remailed 9/11/03

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/648,123	Applicant(s) STANTON, V.
	Examiner Cynthia B Wilder	Art Unit 1637

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Feb 24, 2003* .

2a) ☐ This action is **FINAL.** 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *27-34* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *27-34* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 2/24/2003 has been entered. Claims 17-26 have been canceled. Claims 27-34 have been added.

Specification

2. The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code at pages 53, 93-95, 100, 102, 104, 105, 137. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

Claim Rejections - 35 USC § 101 (Lack of Utility)

3. The pending claims 27-34 have been reviewed in light of the Utility Examination Guidelines and Guidelines for Examination of Patent Application under 35 U.S.C. 112, first paragraph, "Written Description" requirement, Federal Register, Vol. 66, No. 4, pages 1092-1111, Friday, January 5, 2001.

The examiner is using the following definitions in evaluating the claims for utility:

> Credible Utility" - Where an Applicant has specifically asserted that an invention has a particular utility, that assertion cannot simply be dismissed by Office personnel as being "wrong". Rather, Office personnel must determine if the assertion of utility is credible (i.e., whether the assertion of utility is believable to a person of ordinary skill in the art based on

the totality of evidence and reasoning provided). An assertion is credible unless (A) the logic underlying the assertion is seriously flawed, or (b) the facts upon which the assertion is based is inconsistent with the logic underlying the assertion. Credibility as used in this context refers to the reliability of the statement based on the logic and facts that are offered by the Applicant to support the assertion of utility. A *credible* utility is assessed from the standpoint of whether a person of ordinary skill in the art would accept that the recited or disclosed invention is currently available for such use. For example, no perpetual motion machines would be considered to be currently available. However, nucleic acids could be used as probes, chromosome markers, or forensic or diagnostic markers. Therefore, the credibility of such an assertion would not be questioned, although such a use might fail the *specific* and *substantial* tests (see below).

"Specific Utility" - A utility that is *specific* to the subject matter claimed. This contrasts with a *general* utility that would be applicable to the broad class of the invention.

"Substantial utility" - a utility that defines a "real world" use. Utilities that require or constitute carrying out further research to identify or reasonably confirm a "real world" context of use are not substantial utilities.

"Well established utility" - a specific, substantial, and credible utility which is well known, immediately apparent, or implied by the specification's disclosure of the properties of a material, alone or taken with the knowledge of one skilled in the art. "Well established utility" does not encompass any "throw away" utility that one can dream up for an invention or a nonspecific utility that would apply to virtually every member of a general class of materials, such as proteins or DNA.

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

4. Claims 27-34 are rejected under 35 U.S.C. 101 because the claimed invention lacks patentable utility due to its not being supported by either specific and/or substantial utility or a well established utility.

The claimed isolated nucleic acid probe comprising at least 15 nucleotides which hybridizes under stringent conditions to a variant human cytochrome P-450 (CYP3A4) gene having a T to C variance at nucleotide 732 and does not hybridize under stringent conditions to a human cytochrome P-450 (CYP3A4) gene not having a T to C variance at nucleotide 732 is not supported by a specific asserted utility because the disclosed use of the isolated nucleic acid molecule is not specific and is generally applicable to any nucleic acid molecule. For example, the specification at pages 26-28 disclose the isolated nucleic acid molecule as useful as a probe in hybridization reactions or primers in an amplification reaction to specifically identify variant forms of a gene, such as the genes recited in Table 3. These are all non-specific uses that are applicable to nucleic acids in general and are not particular or specific to the nucleic acids claimed.

The claimed invention is not supported by a substantial utility because no substantial utility has been established for the claimed isolated nucleic acid molecule or gene product. For example, the specification teaches that the isolated nucleic acid is used as a probe to specifically identify variant forms of a gene, such as a T to C substitution at position 732 of the cytochrome P-450 (CYP3A4) gene. The specification states that the variant form(s) of a gene as listed in the cited Table 3, e.g., the T to C substitution at position 732 of the CYP3A4 gene, is associated with a response to a drug. The specification continues by stating that the frequency of a specific variance or variant form of the gene may correspond to the frequency of an efficacious response to administration of a drug. The specification does not provide any evidence of the claimed variances recited in Table 3, such as the T to C substitution at position 732 of the CYP3A4 gene as being

associated with any drug response, drug metabolism or is capable of modulating or altering the expression or activity of an encoded protein. Additionally, the specification does not provide any evidence that the claimed variance identified by the claimed isolated nucleic acid probe is associated with any diseases or disease conditions. The specification only speculates that the claimed variance is indeed functional. Hence, the need for further research is clearly necessary to determine the function of the claimed variant as being associated with a drug response or a substantial utility. A starting material that can only be used to produce a final product does not have substantial asserted utility in those instances where the final product is not supported by a specific and substantial utility. In this case the claimed nucleic acid probe does not have an asserted or identified specific and substantial utilities or the claimed variant being identified by the probe. The research contemplated by Applicant overall to characterize potential protein products, especially their biological activities does not constitute a specific and substantial utility. Identifying and studying the properties of a protein or gene itself or the mechanisms in which the protein or gene is involved does not define a "real world" context or use. Similarly, the claimed use of identifying probes to detect variances with no asserted function is neither substantial nor specific due to being generic in nature and applicable to a myriad of nucleic molecules as noted by the plethora of nucleic acid molecules denoted in Table 3. Note, because the claimed invention is not supported by a specific and substantial asserted utility for the reasons set forth above, credibility has not been assessed.

Claims 27-34 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well

established utility for the reasons set forth above, one skilled in the art would not know how to use the claimed invention.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the Applicant regards as his invention.

7. Claims 27-34 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

(a) Claims 27-34 are indefinite at "stringent conditions" because the hybridization conditions have not been defined in the specification or claims and it cannot be determined what is considered as "stringent" relations to the hybridization conditions.

Conclusion

8. No claims are allowed. However, the claims are free of the prior art.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Cynthia Wilder whose telephone number is (703) 305-1680. The examiner can normally be reached on Monday through Thursday from 9:30 am to 6:30 pm and on Friday from 9:30 am to 1:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion, can be reached at (703) 308-1119. The official fax phone number for the Group is (703) 308-4242. The unofficial fax number is (703) 308-8724.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group's Patent Analyst, Monica Graves at (703) 305-3002 or Group's receptionist at (703) 308-0196.

Cynthia B. Wilder, Ph.D.

March 12, 2003

KENNETH R. HORLICK, PH.D
PRIMARY EXAMINER
3/17/03